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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/060,872 04/15/98 ESTELL

D GC527

HM22/1030
GENENCOR INTERNATIONAL INCORPORATED
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EXAMINER

SAUNDERS, D

ART UNIT	PAPER NUMBER
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1644

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DATE MAILED: 10/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

060,872

Applicant(s)

ESTELL et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/12/00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 13-14 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 13-14 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 19
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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The request filed on 7/12/00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/060,872 is acceptable and a CPA has been established. An action on the CPA follows.

Claim 13-14 are pending and under examination.

The amendment of 7/12/00 (Paker 18) has entered no new matter.

The amendment has overcome the previously stated basis of rejection under 35 USC 112, second paragraph.

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garman et al (5,820,862) in view of Bhardwaj et al (J. Clin. Invest 1994) and Mackay et al.

Garman et al have been previously cited (papers 8 and 15) for teaching the identification of T-cell epitopes within a protein allergen and the modification thereof (e.g. via substitution of amino acid residues) to provide peptides which induce a lowered or not any proliferative response. As applicant has correctly stated in the response of Paper 18, Garman et al fail to teach the use of naive T-cells. Rather they teach epitope screening with T-cells from sensitized individuals.

Bhardwaj et al. Teach methods by which CD4+ or CD8 T-cells may be obtained from peripheral blood cells from naive individuals. They also teach how to obtain dendritic cells (Dcs) from the same peripheral blood sample. They teach how to use the separated DCs to induce a cytotoxic response of CD8+ cells or a proliferative response of CD4+ cells against a virus. They

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show that DCs are the most efficient of all cell types tested for antigen presentation. Applicant is referred to pages 798-799 for methods.

Bhardwaj et al. are thus noted for teaching that CD4+ CD8+ responses to an antigen can be assessed with the use of naive T-cells from a peripheral blood sample if DCs from the sample are used as the antigen presenting cells.

Mackay et al. teach the obtaining of immortal DCs via the use of a differentiation inducing medium having constituents (GM-CSF as the major one). Mackay et al. teach that the obtained Dcs can be used for epitope mapping by testing with a large number of synthetic peptides (col. 9 line 16+). Like Bhardwaj et al., Mackey et al. teach that DCs are the most potent antigen presenting cell type and that they can present to naive T-cells (col. 1, lines 53+ and col. 9, lines 34+).

From the combination of the above cited prior art it would have been obvious to screen for T-cell epitopes within an allergic protein and to screen for lowered or abrogated T-cell reactivity against modified T-cell epitopes via the use of naive peripheral blood T-cells as taught Bhardwaj et al and/or MacKay et al, with the use of DCs to present the epitopic peptides. Motivation to do so would have been to gain the advantage of being able to use T-cells from any, naive individual instead of only from sensitized individuals. This would have been an expected advantage when one needed to conduct large scale screening programs--e.g. using large numbers of modified epitopic sequences. By being capable of using naive T-cells from any individual one

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would have had a larger number of individuals available for providing the T-cells and the supply of such for large scale screening programs would have not been a limiting factor.

Applicant's urgings filed 7/12/00 have been considered but are unconvincing in light of the new combination of reference cited.

The previously stated rejection based on Fehlner et al has been withdrawn, since there would be little motivation to use naive T-cells in lieu of the T-cell lines or primed T-cells used by Fehlner et al.

The newly cited Bhardwaj et al. and MacKay et al references have not been provided to applicant; copies of these were provided during examination of copending divisional application 255,505.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders Ph.D. whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Friday from 8:15 to 4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Saunders/sg

10-17-00

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644